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06/03/2002

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EXAMINER

BANSAL, GEETHA P

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 06/03/2002

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/194164

Applicant(s)

Dan et al

Examiner

G. Bansal

Group Art Unit

1642

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 1/9/02, 2/25/02
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☐ Claim(s) 1-25, 39-50, 51-85 is/are pending in the application.
- Of the above claim(s) 1-25, 39-50 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 51-85 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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DETAILED ACTION

1. Applicant's amendment filed 1/9/02 and 2/25/02 (Paper No: 13/B and 19/C) are acknowledged. Accordingly, claims 26-38 have been cancelled and claims 51-84⁸⁵ have been added.

Claims 51-84 are being examined.

Response to Arguments

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 51-84⁸⁵ are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 51 is indefinite because it is unclear as to what entity the antigen binding fragment competitively inhibits.

B. It is not clear in claim 51 what the metes and bounds are of the "fragment" of the antibody whose Lv and Hv are comprised in SEQ ID 14.

C. Claim 59 is not clear which antibody fragment is inhibited by the "antigen binding fragment encoded by the first polynucleotide".

D. The metes and bounds of stringent conditions are not clearly set out in claims 59, 64-68.

E. In claims 51 and the dependent claims therefrom, it is not clear if the tumor cell surface epitope that competitively inhibits specific binding, as recited in claim 59, is the same as the hexapeptides displayed on the phage, recited in the dependent claims, or related to each other.

4A. The rejection of claims 51, 59, 69-84 under 35 U.S.C. 112, lack of written description is maintained. Applicant's arguments and amendments have been considered but they are not

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persuasive. Applicant argues that the claims have been amended such that it no longer requires isolation of the C antigen to make the claimed antibodies. However, it is still not deemed to have obviated the rejection because the claims still read on a polynucleotide encoding an antigen binding fragment that binds to a tumor cell surface epitope, which is also recognized by an antibody having the sequence depicted by SEQ ID No 14. The amendment reciting "competitively inhibits binding to a tumor cell surface epitope" does not render the claims as sufficiently described (see rejection under 112, 2nd paragraph), because the claim does not provide a nexus between the claimed antibody and the antibody having SEQ ID No 14. As such the claim still requires the availability of the antigen (in this case the C antigen) to practice the claimed invention. Amending claims further to indicate that the claimed antibody competitively inhibits the binding of the antibody having SEQ ID No 14 to the tumor cell epitope that is bound by the antibody having SEQ ID NO 14 may be able to render the claims free of the art.

4B. Rejection of claims 37-38 under 35 U.S.C. 1st paragraph as being non enabled for pharmaceutical compositions is withdrawn in view of the cancellation of the claims.

5. No claims are allowed.

6. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal

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Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-3014.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Geetha P. Bansal whose telephone number is (703) 305-3955. The examiner can normally be reached on Mondays to Fridays, and alternate Wednesdays from 7:00am to 4:30pm and alternate Fridays from 7:00am to 3:30pm. A message may be left on the examiner's voice mail service.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Anthony Caputa, can be reached on (703) 308- 3995.

9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May 31, 2002



GEETHA P. BANSAL
PRIMARY EXAMINER